Connecticut Cardiovascular Consortium

A statewide organization of Connecticut hospitals and the Office of Health Care Access

Connecticut Cardiovascular Consortium Steering Committee Members

William Boden, M.D., Director of Cardiology, Hartford Hospital

Marcia Bull, M.D., Director, Division of Cardiology, The Stamford Hospital

Henry Cabin, M.D., Division of Cardiology, Yale Univ. School of Medicine

Daniel Diver, M.D., Director of Cardiology,St. Francis Hospital and Medical Center

Mark Fisherkeller, M.D., Chief of Cardiology, Windham Hospital

W. David Hager, M.D., Division of Cardiology, John Dempsey Hospital

Edward Kosinski, M.D., Chief, Division of Cardiology, St. Vincent's Medical Center

Martin Krauthamer, M.D., Section Chief, Cardiology, Norwalk Hospital

Harlan Krumholz, M.D., Director, Center for Outcomes & Evaluation, YNHH

Rose Maljanian, RN, MBA, Dir., Institute for Outcomes Research, Hartford Hospital

Connecticut Cardiovascular Consortium Steering Committee Members

Kimberly Martone, State of Connecticut Office of Health Care Access, Hartford, CT

Arthur McDowell, M.D., Chief of Cardiology, Middlesex Hospital

Raymond McKay, M.D., Interventional Cardiologist, Hartford Hospital

Martha Radford, M.D., Deputy Director, CORE, Yale-New Haven Hospital

Marybeth Reinhardt, State of Connecticut, Office of Health Care Access, Hartford, CT

Milton Sands Jr, M.D., Chief of Cardiology, New Britain General Hospital

Kenneth Schwartz, M.D., Medical Director, Griffin Hospital

Jeffrey Seltzer, M.D., The William W. Backus Hospital

Barry Zaret, M.D., Chief, Cardiology, Yale Univ. School of Medicine

Genesis of C3:

- Following the 1999 Goodman Report, Drs. Boden & Zaret hypothesized that Connecticut's unique constellation of 31 hospitals, excellent cardiovascular practitioners, well-defined referral patterns and clinical outcomes that exceeded national standards provided the basis for collaborative investigation

Genesis of C3 (cont'd):

- In August, 2000, Drs. Boden & Zaret approached the Director,Health Systems Development at OHCA, to enlist his support for developing a collaborative research infrastructure whose goal would be to advance healthcare quality and outcomes for Connecticut residents with cardiovascular disease

Genesis of C3 (cont'd):

- A series of organizational meetings, initiated by Drs. Boden & Zaret among cardiologists at HH & YNHH and facilitated by OHCA, led to the creation of a multidisciplinary, representative Steering Committee, formulation of a preliminary clinical research proposal, and regular meetings/conference calls from April, 2001, to the present...

Why Do We Need a CT Cardiovascular Consortium?

- There are no existing databases for obtaining in-hospital ***and*** 30 day AMI clinical outcomes data within the state of CT; CHIME, NRMI and ACC databases focus on in-hospital mortality only
- There is no existing methodology to evaluate AMI clinical outcomes among tertiary centers and community hospitals within CT in an era of rapidly evolving technologic and pharmacologic innovation
- Creation of C3 can replicate & extend the highly-successful models of collaborative interaction and investigation, such as the TIMI Research Group and Northern New England Cardiovascular Disease Study Group

The Need (cont'd):

- Prospective population-based study may complement and augment both existing registries (NRMI, ACC) and randomized controlled studies of MI management by providing "real-world" data acquisition
- Study outcomes may favorably impact the utilization of emergency medical services within Connecticut
- C3 provides an important vehicle and infrastructure for future cardiac studies
- C3 provides a model to improve quality and outcomes for patients, providers and hospitals

OHCA's Role in C3 *is:*

- To facilitate the development of the Consortium and its first project
- To administer grants secured by the Consortium
- To work proactively with the C3 leadership to ensure broad-based participation of Connecticut hospitals

OHCA's Role in C3 ***is NOT:***

- To dictate/oversee any of the conduct of consortium projets
- To play any role in data collection, retrieval, analysis or interpretation
- To defer or alter the CON review process while C3 projects are planned or underway

What's New and Different?

- First known state-wide prospective observational study devoted to understanding outcomes of care decisions, not procedures.
- Community-based cohort, real-world patients.
- All physicians treating patients with AMI in all hospitals throughout CT are invited to participate.

Purpose of C3:

- to advance the caliber and quality of healthcare of Connecticut residents with cardiovascular disease.
- to obtain high quality, useful process and outcomes data.

Current Treatment for ST-Segment Elevation MI

- ***A. PRIMARY PCI***
- ***B. FACILITATED PCI***
- ***C. PRIMARY THROMBOLYSIS WITHOUT URGENT OR DELAYED CATHETERIZATION***
- ***D. PRIMARY THROMBOLYSIS WITH DELAYED CATHETERIZATION FOR:***
  - Clinical symptoms of recurrent angina
  - Abnormal (ischemic) stress test
  - Routine pattern of care

Deficiencies or Limitations of Thrombolytic Therapy

- 70%-75% of AMI patients are considered ineligible for thrombolytic therapy (cerebrovascular disease, hemorrhagic diatheses, active bleeding, recent surgery, severe hypertension, recent CPR)
- Maximal incidence of infarct-vessel patency (TIMI 2 or 3): 80%
- Maximal incidence of optimal infarct-vessel flow (TIMI 3): 55%-60%

Limitations (cont'd):

- Median lag time of 45 minutes between drug administration and reperfusion
- Lack of clinical markers of successful reperfusion
- 0.5%-1.5% incidence of intracranial bleeding
- 15%-30% incidence of recurrent ischemic events

Deficiencies or Limitations of Urgent Primary Angioplasty

- Only 20% of US Hospitals have suitable facilities and manpower for performance of urgent PCI
- Cost
- 3%-5% incidence of recurrent ischemic events
- Long term efficacy of treatment strategy has not been determined

C3 STEMI Study Proposal

- We propose to undertake a prospective, observational study of Connecticut residents who present with acute ST-Segment Elevation Myocardial Infarction (STEMI) to:
  - assess contemporary clinical practice patterns of STEMI management statewide in 2002-2003
  - compare clinical outcomes in STEMI patients treated with fibrinolytic therapy or primary angioplasty (PCI)

C3 Hospitals

- 30 Acute Care Hospitals in CT
  - 7 tertiary centers capable of performing urgent PCI/surgery
  - 9 hospitals with cardiac cath labs but no PCI/surgery capability
  - 14 hospitals without cath labs

Hypothesis I

Risk-adjusted clinical outcomes (for the primary composite endpoint) in acute STEMI patients who receive primary percutaneous coronary intervention (PCI) as an intended initial treatment strategy within 12 hours of sx-onset will not be significantly different from risk-adjusted clinical outcomes in patients who receive any other treatment strategy.

Hypothesis II

Utilization of primary PCI among non-white patients, as an initial treatment strategy for STEMI and adjusted for other demographic and clinical characteristics, will not be significantly different from the utilization of primary PCI among white patients.

Patient Inclusion Criteria

- Prolonged, continuous (>20 minutes) signs of ischemia not eliminated with nitrates and onset within 12 hours of evaluation, and one of the following:
  - A. ST-segment elevation > 1 mm in two or more contiguous limb ECG leads
  - B. ST-segment elevation > 2mm in two or more contiguous precordial ECG leads
  - C. New (or presumably new) left bundle branch block pattern
  - D. ST segment depression in V_1 and V_2 with R > S consistent with acute posterior MI
- Agree to comply w/ 30 day follow-up

Patient Exclusion Criteria

- AMI onset > 12 hours
- Non ST-segment Elevation MI, unless there is evidence of posterior MI
- Suspected acute pericarditis
- Percutaneous coronary intervention within 6 weeks prior to evaluation
- Participation in any other AMI research study

Primary Endpoint:

- All-cause mortality, recurrent myocardial infarction (MI), repeat hospitalization for biomarker (creatine kinase and/or troponin)-positive acute coronary syndrome (ACS), or stroke at 30 days

Secondary Endpoints:

- Radionuclide left ventricular (LV) ejection fraction (EF) and quantitative infarct size from gated sestamibi SPECT myocardial imaging (30-60 days post-index MI)

Secondary Endpoints (cont'd):

- 6-month clinical follow-up for trial primary composite endpoint
- Major bleeding (using published TIMI criteria)

Proposed Pre-specified Analyses

- Site of presentation (tertiary vs. community) for primary endpoint
- "Drip-and-ship" vs "drip-and-watch" (thrombolysis alone) versus PCI alone
- Analysis of transport/treatment times (time from sx-onset to hospital presentation; time from hospital presentation to tertiary referral; door-to-needle/balloon)
- Facilitated PCI versus PCI alone

Proposed Pre-specified Analyses (continued)

- Facilitates thrombolysis versus thrombolysis alone
- Rescue angioplasty/bail-out PCI
- Cardiogenic shock
- ECG MI location (strategy versus outcome)
- Initial TIMI flow grade in PCI group versus time and pharmacotherapy
- Procedural utilization rates among women, minorities
- Outcomes in diabetics

Study Procedures

- Oversight/Coordination
- Screening
- Enrollment
- Follow-up
- Compensation
- Reporting

Study Organization and Oversight

- CCC Steering Committee: broad oversight and review of procedures and issues.
- Participating Hospitals: patient enrollment and follow-up(site investigator- MD and coordinator-RN).
- Office of Health Care Access: facilitation of participation.
- Hartford Hospital: project management and data acquisition and quality.
- Yale New Haven Health System-CORE: data quality, analysis and reporting.

Screening

- All admitted AMIs (not just STEMIs) will be screened by each site.
- Screening can be done after admission (does not need to be done in ED).
- Screening encounter will be entered into the database with no transfer of identifiers.

Enrollment

- Eligible patients will be enrolled by the initial admitting site.
- Patients' written consent will be obtained.
- Patients' information will be gathered from the medical record by the site coordinator and entered into the secure, password protected web-based tracking database.

Follow-up

- Patient follow-up will be completed by telephone at 30 days and 6 months by the site coordinator.
- If a patient has been transferred, follow-up will be completed by the enrolling site.

Compensation to Sites*

- $50 for each patient screened.
- $100 for each patient enrolled.
- $50/$50 for completion of 30 day and 6 month follow-up calls.

*Draft figures- pending review of final proposal and funding agency decision.

Data Confidentiality

- Data stored on a password secure workstation
- Persons responsible for data will sign an agreement that they will maintain security of the data registry and will not use or release data for any other purpose unless prior written permission of the consortium has been secured
- Site, physician and patient specific specifiers will be encrypted and ID decoder kept in locked storage area
- All participants will sign an appropriate participation agreement and release
- Data protected under Connecticut statute from discoverability

Ensuring Study/Data Quality

- Screening
  - Goal: 100% but no less than 80% to consider the study sample representative. To be verified quarterly against each hospital's administrative database.
- Enrollment
  - Goal: >80% eligible patients consented.
- Audits of charts and interviews to be conducted by central team.

Reporting

- Data quality reports will be issued to the individual sites throughout the study.
- At the close of the study, aggregate reports will be provided to all participating CCC members, including OHCA. Reports will not contain any identifiable patient, physician or hospital information.

Opportunity that C3 Represents

In addition to evaluating the primary hypothesis, we will:

- Assemble a unique community-based STEMI cohort close to 100%.
  - Enable learning about treatment strategies and outcomes in understudied groups.
- Establish a precedent for collaborative state-wide clinical investigation in CT.

Implications of Study Results

- Prospective data acquisition will provide comprehensive survey of contemporary practice patterns within Connecticut
- Identification of "best practices" for managing ST-segment elevation MI may favorably impact practice patterns of Connecticut physicians
- CCC initiative can be linked to statewide educational initiatives to heighten patient awareness of the need for immediate medical evaluation and treatment

Outstanding Issues For Discussion and Resolution

- Finalization of protocol
- Reassurance that there is no “hidden agenda” to use C3 for purposes other than advancing best practices through collaborative clinical research.
- Reassurance that electronic data entry will be user-friendly, confidential and that capitated reimbursement for site personnel will be secured from outside funding sources.

Issues For Discussion/Resolution (cont'd.)

- Buy-in & participation of all hospitals.
- Projected timelines for initiation and completion.
- Funding update